IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA LTD. and VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE S.A.S.,	)	
Plaintiffs,	)	C.A. No. 18-390-LPS
v.	)	
LUPIN ATLANTIS HOLDINGS SA, LUPIN PHARMACEUTICALS, INC., and TEVA PHARMACEUTICALS USA, INC.	)	
Defendants.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor Fresenius Medical Care Renal Pharma Ltd. ("VFMCRP Switzerland") and Vifor Fresenius Medical Care Renal Pharma France S.A.S. ("VFMCRP France") (collectively, "Plaintiffs" or "Vifor Fresenius") hereby assert the following claims for patent infringement against Defendants Lupin Atlantis Holdings SA ("Lupin Atlantis") and Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") (collectively, "Lupin"), and Teva Pharmaceuticals USA, Inc. ("Teva"), and allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 9,561,251 as corrected by the Certificate of Correction that issued on August 13, 2019 ("the '251 patent") under the laws of the United States, 35 U.S.C. § 100, *et seq.* arising from Lupin's and Teva's filing of Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Plaintiffs' VELPHORO® drug product prior to the expiration of the '251 patent.

THE PARTIES

2. Plaintiff VFMCRP Switzerland is a corporation organized and existing under the laws of Switzerland with its principal place of business at Rechenstraße 37, St. Gallen, 9011, Switzerland.

3. Plaintiff VFMCRP France is a simplified joint stock company (*société par actions simplifiée*) organized and existing under the laws of the Republic of France which has its principal place of business at 100-101 Terrasse Boieldieu Tour Franklin La Défense 8 F-92042 Paris La Défense Cedex, France. VFMCRP France is a wholly-owned subsidiary of VFMCRP Switzerland.

4. On information and belief, defendant Lupin Atlantis is a corporation organized and existing under the laws Switzerland, with a principal place of business at Landis & Gyr – Strasse 1, 6300 Zug, Switzerland.

5. On information and belief, defendant Lupin Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Lupin Pharmaceuticals is a wholly owned direct or indirect subsidiary of Lupin Atlantis.

6. On information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

THE ’251 PATENT

7. On February 7, 2017, the PTO issued U.S. Patent No. 9,561,251, entitled “Pharmaceutical compositions.” The inventors of the ’251 patent are Ludwig Daniel Weibel and Erik Philipp. VFMCRP Switzerland is the assignee of the ’251 patent. On August 13, 2019, the PTO issued a Certificate of Correction regarding the ’251 patent. A copy of the ’251 patent, as corrected by the Certificate of Correction, is attached hereto as Exhibit A.

THE VELPHORO® DRUG PRODUCT

8. VFMCRP France holds an approved New Drug Application (“NDA”) under Section 505(a) of the Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(a), for sucroferric oxyhydroxide chewable tablets, 500 mg (NDA No. 205109), sold under the trade name VELPHORO®. VELPHORO® is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis. VFMCRP France received approval for VELPHORO® from the FDA in November 2013.

9. The claims of the ’251 patent cover, *inter alia*, pharmaceutical formulations containing sucroferric oxyhydroxide.

10. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the ’251 patent is listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), in connection with VELPHORO®.

ACTS GIVING RISE TO THIS ACTION

11. On information and belief, Lupin Atlantis submitted Abbreviated New Drug Application No. 211386 (the “Lupin ANDA”) to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). On information and belief, the Lupin ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of a sucroferric oxyhydroxide chewable tablets, 500 mg,(the “Lupin Proposed ANDA Product”), a generic version of

VELPHORO®. The Lupin ANDA specifically seeks FDA approval to market the Lupin Proposed ANDA Product prior to the expiration of the '251 patent.

12. On information and belief, following any FDA approval of the Lupin ANDA, Lupin will make, use, offer to sell, or sell the Lupin Proposed ANDA Product throughout the United States, or import such generic products into the United States.

13. On or about January 29, 2018, Vifor Fresenius received a letter dated January 26, 2018 from Lupin Atlantis's counsel stating that the Lupin ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Lupin Paragraph IV Certification"), which provides that, in Lupin Atlantis' opinion, the '251 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale" of the Lupin Proposed ANDA Product.

14. This action is being commenced before the expiration of 45 days from the date Vifor Fresenius received the Lupin Paragraph IV Certification Letter.

15. On information and belief, Teva submitted Abbreviated New Drug Application No. 211411 (the "Teva ANDA") to the FDA under § 505(j) of the FFDCA (21 U.S.C. § 355(j)). On information and belief, the Teva ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of a sucroferric oxyhydroxide chewable tablets, 500 mg, (the "Teva Proposed ANDA Product"), a generic version of VELPHORO®. The Teva ANDA specifically seeks FDA approval to market the Teva Proposed ANDA Product prior to the expiration of the '251 patent.

16. On information and belief, following any FDA approval of the Teva ANDA, Teva will make, use, offer to sell, or sell the Teva Proposed ANDA Product throughout the United States, or import such generic products into the United States.

17. On or about February 6, 2018, Vifor Fresenius received a letter dated February 5, 2018 from Teva's counsel stating that the Teva ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Teva Paragraph IV Certification"), which provides that, in Teva's opinion, the '251 patent is "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale" of the Teva Proposed ANDA Product.

18. This action is being commenced before the expiration of 45 days from the date Vifor Fresenius received the Teva Paragraph IV Certification Letter.

JURISDICTION AND VENUE OVER LUPIN

19. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

20. This Court has personal jurisdiction over Lupin Atlantis because, *inter alia,* Lupin Atlantis has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of the Lupin ANDA, Lupin Atlantis will make, use, offer for sale, sell, and/or import the Lupin Proposed ANDA Product in the United States, including in Delaware, prior to the expiration of the '251 patent.

21. This Court also has personal jurisdiction over Lupin Atlantis because Lupin Atlantis has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Lupin Atlantis regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware. On information and belief, Lupin Atlantis derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

22. On information and belief, Lupin Atlantis has continuously placed its products into the stream of commerce for distribution and consumption in the State of Delaware, and throughout the United States, and thus has engaged in the regular conduct of business within this Judicial District.

23. On information and belief, Lupin Atlantis derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this Judicial District.

24. On information and belief, Lupin Atlantis has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in prior patent cases. On information and belief, Lupin Atlantis has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *Sanofi v. Lupin Atlantis Holdings S.A.*, C.A. No. 15-415 (RGA) (D. Del.), *Unimed Pharms. LLC v. Lupin Atlantis Holdings SA*, C.A. No. 1:15-cv-00904-RGA (D. Del.).

25. Additionally, on information and belief, Lupin Atlantis has availed itself of the benefits of this forum by bringing civil actions for patent infringement in this forum in at least the following cases: *Lupin Atlantis Holdings SA v. Ranbaxy Labs. Limited*, C.A. 1:10-cv-00659-SLR (D. Del.), *Lupin Atlantis Holdings SA v. Apotex Inc.*, C.A. 1:11-cv-00234-LPS (D. Del.), and *Lupin Atlantis Holdings SA v. InvaGen Pharms. Inc.*, 1:16-cv-00708-SLR-SRF (D. Del.).

26. In the alternative, this Court has jurisdiction over Lupin Atlantis because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Vifor Fresenius's claims arise under federal law; (b) Lupin Atlantis is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Atlantis has sufficient contacts with the United States as a whole, including, but not limited to, participating in the preparation and submission of the Lupin ANDA for the Lupin Proposed ANDA Product to the FDA and/or

manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Atlantis satisfies due process.

27. This Court has personal jurisdiction over Lupin Pharmaceuticals because, *inter alia*, Lupin Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware.

28. On information and belief, Lupin Pharmaceuticals operates and acts as the agent of Lupin Atlantis and is controlled by Lupin Atlantis, particularly with respect to marketing Lupin's generic pharmaceutical products throughout the United States. For example, Lupin Pharmaceuticals' 2017 financial statements contain a related-party disclosure stating that Lupin Pharmaceuticals' relationship with Lupin Atlantis is one "where control exists." Lupin Pharmaceuticals, Inc. Audited Accounts for the Year Ended March 31, 2017 at 11, http://www.lupin.com/pdf/17/07/subsidiaries/Lupin-Pharmaceuticals-Inc-USA.pdf (last visited Feb. 28, 2018).

29. Venue is proper for Lupin Atlantis under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia,* Lupin Atlantis is a foreign corporation and is subject to personal jurisdiction in this Judicial District, as set forth above. In addition, Lupin Atlantis has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth in paragraph 21 above, and continuously transacts business in this Judicial District, as set forth in paragraph 22-27 above.

30. Venue is proper for Lupin Pharmaceuticals under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Lupin Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware.

JURISDICTION AND VENUE OVER TEVA

31. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

32. This Court has personal jurisdiction over Teva because, *inter alia*, Teva is a corporation organized and existing under the laws of the State of Delaware.

33. Venue is proper for Teva under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Teva is a corporation organized and existing under the laws of the State of Delaware.

COUNT II: INFRINGEMENT OF THE '251 PATENT BY LUPIN

34. Vifor Fresenius repeats and realleges paragraphs 1-33 above as if fully set forth herein.

35. By filing the Lupin ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Lupin Proposed ANDA Product before the expiration of the '251 patent, Lupin Atlantis committed an act of infringement under 35 U.S.C. § 271(e)(2).

36. On information and belief, if Lupin commercially makes, uses, offers to sell, or sells the Lupin Proposed ANDA Product within the United States, or imports the Lupin Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the '251 patent, Lupin will further infringe at least claims 1, 10, 21, 24, 34, 35, 36, 38, 39, and 40 of the '251 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, in order to claim bioequivalence between the Lupin Proposed ANDA Product and VELPHORO®, Lupin was required to select an oral dosage form containing approximately 800 mg of iron oxy-hydroxide and saccharose (sucrose) and a starch, thereby establishing infringement of the '251 patent. In addition, the Lupin Paragraph IV certification does not dispute that it infringes at least claim 1 of the '251 patent.

37. Lupin Atlantis has had knowledge of the ’251 patent since at least the date Lupin Atlantis submitted the Lupin ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). Lupin Pharmaceuticals has had knowledge of the ’251 patent by at least the date of service of this Complaint.

38. Plaintiffs will be irreparably harmed if Lupin is not enjoined from making, selling, using or importing the Lupin Proposed ANDA Product, which upon information and belief will infringe the ’251 patent. Plaintiffs do not have an adequate remedy at law.

COUNT III: INFRINGEMENT OF THE ’251 PATENT BY TEVA

39. Vifor Fresenius repeats and realleges paragraphs 1-38 above as if fully set forth herein.

40. By filing the Teva ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of the Teva Proposed ANDA Product before the expiration of the ’251 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

41. On information and belief, if Teva commercially makes, uses, offers to sell, or sells the Teva Proposed ANDA Product within the United States, or imports the Teva Proposed ANDA Product into the United States, or induces or contributes to any such conduct during the term of the ’251 patent, Teva will further infringe at least claims 1, 10, 21, 24, 34, 35, 36, 38, 39, and 40 of the ’251 patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Upon information and belief, in order to claim bioequivalence between the Teva Proposed ANDA Product and VELPHORO®, Teva was required to select an oral dosage form containing approximately 800 mg of iron oxy-hydroxide and saccharose (sucrose) and a starch, thereby establishing infringement of the ’251 patent. In addition, the Teva Paragraph IV certification does not dispute that it infringes at least claim 1 of the ’251 patent.

42. Teva has had knowledge of the ’251 patent since at least the date Teva submitted its ANDA and was aware that submission of its ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2).

43. Plaintiffs will be irreparably harmed if Teva is not enjoined from making, selling, using or importing its Proposed ANDA Product, which upon information and belief will infringe the ’251 patent. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Lupin has infringed one or more claims of the ’251 patent by filing the Lupin ANDA;

B. A Judgment that Lupin has infringed, and that Lupin’s making, using, offering to sell, selling, or importing the Lupin Proposed ANDA Product would constitute infringement of one or more claims of the ’251 patent, and/or induce or contribute to the infringement of one or more claims of the ’251 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

C. A permanent injunction restraining and enjoining Lupin, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Lupin Proposed ANDA Product until after the expiration of the ’251 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. An Order that the effective date of any approval of the Lupin ANDA relating to the Lupin Proposed ANDA Product be a date that is not earlier than the expiration date of the ’251 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

E. A Judgment that Teva has infringed one or more claims of the ’251 patent by filing the Teva ANDA;

F. A Judgment that Teva has infringed, and that Teva’s making, using, offering to sell, selling, or importing the Teva Proposed ANDA Product would constitute infringement of one or more claims of the ’251 patent, and/or induce or contribute to the infringement of one or more claims of the ’251 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c);

G. A permanent injunction restraining and enjoining Teva, and its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Teva Proposed ANDA Product until after the expiration of the ’251 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

H. An Order that the effective date of any approval of the Teva ANDA relating to the Teva Proposed ANDA Product be a date that is not earlier than the expiration date of the ’251 patent as extended plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

I. Such other and further relief as the Court may deem just and proper.

Date: September 11, 2019

FARNAN LLP

s/ Brian E. Farnan

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